

Remarks

I. Status of the Claims

Claims 1-10, 12, 13, and 15-59 are pending in this application. Claims 57 and 58 were withdrawn from consideration by the Examiner. Claims 12 and 13 have been amended to clarify that the melting point limitation therein refers to the at least one thermal transition agent. These amendments are supported by the specification as originally filed and thus raise no issue of new matter. Moreover, these amendments do not narrow the scope of claims 12 and 13.

Applicants thank the Examiner for indicating the allowable subject matter of claim 19. Applicants maintain that the remaining claims are patentable, however, and wish to continue prosecution of this application in view of the preceding amendments and following remarks. Additionally, Applicants thank the Examiner for withdrawing the enablement rejection under 35 U.S.C. § 112, the anticipation rejection under 35 U.S.C. § 102 over Hoefer et al. (U.S. Patent No. 5,312,865), and the obviousness rejection under 35 U.S.C. § 103(a) over Hoefer et al.

II. Rejections under 35 U.S.C. § 112

A. Indefiniteness Rejection

The Examiner maintained the rejection of claims 12 and 13 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Office Action at page 2. Specifically, the Examiner states that there is insufficient antecedent basis for “the melting point” limitation because “[i]t is not clear whether the limitation refers to the melting point of the composition or to the melting point of any composition

components." *Id.* Applicants respectfully assert that this rejection has been rendered moot by the foregoing amendments to claims 12 and 13 wherein it is clear that the limitation refers to the melting point of the at least one thermal transition agent.

Accordingly, for at least these reasons, Applicants request that this ground of rejection be withdrawn.

B. Written Description Rejection

The Examiner rejected claims 1-10, 12, 13, 15-18, 20-56 and 59 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the claims contain subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Office Action at page 3.

Specifically, the Examiner stated

There are semi-crystalline polymers that would be encompassed by the claim, that are not described in the specification. The instant claims recite a genus of semi-crystalline compounds that are defined only by their transition temperature and lack of water solubility at a temperature below the transition temperature. To provide evidence of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus . . . the specification does not provide adequate written description of the claimed genus because one skilled in the art can not structurally visualize any semi-crystalline thermal transition agents, except for the single disclosed polycaprolactones; thereby, not reasonably meeting the written description requirements of 35 U.S.C. 112, first paragraph.

Office Action at pages 3 and 4.

Applicants respectfully traverse this rejection. A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been

presented by the examiner to rebut the presumption. M.P.E.P. § 2163, III. A. at 2100-176. The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. *Id.* The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Id.* In rejecting a claim, the Examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion.

The Examiner has not met this burden in the present case. The Examiner concedes that the specification provides adequate written description support for the polycaprolactones species. Office Action at page 4. Notably, however, Federal Circuit case law establishes that a single species can provide adequate written description support for a larger genus where the disclosure provides sufficient information and guidance that one skilled in the art would readily know the other members of the genus that could be used. See *e.g., Utter v. Hiraga*, 845 F.2d 993 (Fed. Cir. 1988) (affirming ruling that applicant's Japanese specification that described in detail scroll mechanism with an internal pivot and while not expressly claiming an external pivot, did not disclaim an external pivot and cited prior art that described external pivots, supported a generic count in an interference that was silent as to location of the pivot point); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279 (CCPA 1973) (reversing PTO's written description rejection of claims that claimed the use of an "inert fluid" in a claimed method, where the written description and the claims as originally filed only described the use of "air or other inert gas" because the specification connoted that the important functional aspect of matter required fluid characteristics, and therefore, the use of a liquid/fluid was

inherently disclosed); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004) (“[T]his court has continued to apply the rule that disclosure of a species may be sufficient written description support for a later claimed genus including that species”)

Although there are exceptions to the general rule that the disclosure of a species provides sufficient written description support for a later filed claim directed to the genus, it is limited to cases in which “the difference between members of the group is such that the person skilled in the art would not readily discern that other members of the genus would perform similarly to the disclosed members. . . .” *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1125 (Fed. Cir. 2004). In this case, however, it is abundantly clear that the other members of the genus would perform similarly by the fact that the genus is functionally defined, i.e., by the transition temperature range and lack of water solubility below the transition temperature of the semi-crystalline compounds in the genus.

Moreover, the Examiner cites no authority for the proposition that the absence of the recitation of structure alone is a sufficient reasonable basis to challenge the adequacy of the written description. Indeed, the Examiner, by his own admission, concedes that structure is only *one factor* to be considered. Office Action at page 4. Applicants respectfully assert that other factors, such as the genus being defined by its recited properties, would serve to describe the claimed invention.

Accordingly, for at least these reasons, Applicants request that this ground of rejection be withdrawn.

III. Rejection Under 35 U.S.C. § 102

The Examiner has rejected claims 1-10, 12, 13, 15-18, 20-25, 46, 47 and 52-56 under 35 U.S.C. § 102(b) as being anticipated by Hayashi et al. (EP Patent No. 367 015) ("Hayashi") for the reasons disclosed on pages 4 and 5 of the Office Action.

Specifically, the Examiner alleges that

The make-up material of Hayashi et al. "could be washed away easily using warm water at around 42-43⁰ C." . . . With respect to the claimed hot and cold water resistance, these limitations are inherent in the reference because the reference teaches the same polymer as disclosed herein and also teaches water-solubility of the composition in warm water having temperature above the glass transition temperature of the polymers.

Office Action at page 5.

Applicants respectfully traverse this rejection. The Examiner has not shown that the prior art reference, either expressly or inherently, teaches each and every limitation of the claim, the standard for anticipation. See M.P.E.P. § 2131. The Examiner implies that simply because Hayashi teaches polyurethanes with allegedly the same molecular weight and hydroxyl numbers, that the reference necessarily teaches a cosmetic composition capable, at the temperature of the keratinous material, of forming a film having a resistance (Rc) to hot water maintained at 40°C, of less than or equal to 15 minutes, and a resistance (Rf) to cold water, maintained at 20°C such that $R_f - R_c \geq 8$ minutes. The Examiner, however, has provided no basis in fact and/or technical reasoning to reasonably support this determination as the Examiner is required to do. M.P.E.P. § 2112 at 2100-55.

This rejection is improper because the Examiner has not shown that compositions like Hayashi necessarily and inevitably, the standard for inherency, meet

the claim limitations. Again, Applicants reiterate, as they have done throughout the prosecution of this case, that inherent anticipation arises only when “the prior art *necessarily* functions in accordance with, or includes, the claimed limitations.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (emphasis added). Inherency may not be established by probabilities or possibilities. *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268-69 (Fed. Cir. 1991).

Moreover, the Examiner has not even addressed the claim limitation of all the pending claims, for example, “the at least one thermal transition agent being not water-soluble in water maintained at a temperature below the transition temperature.” Although the Examiner alleges that the cited reference teaches water-solubility of the composition in warm water having temperature above the glass transition temperature of the polymers, Office Action at page 5, the Examiner makes no mention of the water-insolubility limitation of the at least one thermal transition agent below the transition temperature.

For at least these reasons, Applicants respectfully submit that the standard for anticipation has not been met. Accordingly, Applicants request that this ground for rejection be withdrawn.

IV. Double Patenting Rejection

The Examiner has provisionally rejected claims 1-10, 12, 13, 15-18, 20-56 and 59 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1- 30, 32-37, 45 and 46 of copending Application No. 10/138,325 (“the '325 application”). Office Action at page 6. The Examiner asserts that, although the claims are not identical, they are not patentably distinct from each other

because the presently claimed invention overlaps with that claimed in the '325 application. Office Action at page 6.

Applicants request that this ground for rejection be held in abeyance until the other rejections of record have been overcome.

VI. Conclusion

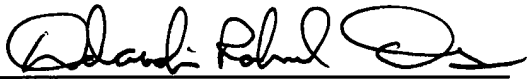
In view of the foregoing amendment and remarks, Applicants respectfully request the reconsideration of this application, and timely allowance of the pending claims. If the Examiner believes a telephone call could be useful in resolving any outstanding issues, she is invited to contact Applicant's undersigned counsel at 202-408-4388.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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